OTHER TRANSACTION AGREEMENT (OTA)

OTHER TRANSACTION FOR ADVANCED RESEARCH (OTAR)

BETWEEN

Regeneron Pharmaceuticals, Inc.
777 Old Saw Mill River Road
Tarrytown, New York 10591-6717

AND

THE UNITED STATES OF AMERICA
DEPARTMENT OF HEALTH AND HUMAN SERVICES
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
200 C Street, S.W.
WASHINGTON, DC 20515

CONCERNING

Novel Antibodies against Influenza Virus, Emerging, re-Emerging, and pre-Emerging pathogens

Modification No. 0003

Date: May 28, 2019

PR No.: OS233799 ($19,274,081) and OS236412 ($278,812)

Total Amount of the Agreement: $47,807,634 (Changed)
Total Estimated Government Funding of the Agreement: $38,246,106 (Changed)
Total Estimated Recipient Funding of the Agreement: $9,561,528. (Changed)
Funds Obligated: $38,246,106 (Changed)
Period of Performance: September 30, 2017 through June 30, 2022 (Changed)

Authority: Section 319L(c) (4) (B) and/or 319L(c) (4) (D) of the Pandemic and All-Hazards Preparedness Act, P.L. 109-417

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027 (b)(4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 199TWLN (b)(4) (CLIN 0001)

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994047 (b)(4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class 25106, Appropriation Yr: 2017, CAN: 1994044 (b)(4) (CLIN 0001).

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 1994027 (b)(4) (CLIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2017, CAN: 199TWLN (b)(4) CLIN 0003)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 199TWRY (b)(4) CLIN 0001 and (b)(4) LIN 0002)

Line of Accounting and Appropriation: Object Class: 25106, Appropriation Yr: 2019, CAN: 1992019 ($278,812) (CLIN 0001)

PURPOSE: The purpose of this modification is to (1) Add funds to CLIN 0001 (Base), CLIN 0002 (Option 1); (2) add "monoclonal antibodies, drugs or other therapies" phrase to the Introduction and subject invention definition, (3) Revise the period of performance (4) Change the JOC members listing; (5) Revise the POC;(6) Change the POC for payments; (7) add "monoclonal antibodies, drugs or other therapies" to Article VIII Other Terms and Conditions (Property Produced Under this Agreement), and (8) Replace Attachment 1: SOW revision dated March 8, 2019.

Beginning with the effective date of this modification, the Government and Other Transaction Agreement holder mutually agree as follows:

1. Agreement No.:
   HHSO100201700020C Line Items and corresponding values:

   Funding for this OTA is revised as follows:

Line Item	Recipient Cost-Share	Government Cost-Share	Total Estimated Cost	Total Government Funds Obligated to Date
0001 - Base Period	(b)(4)			$11,262,666
0002 - Option 1				$18,494,700
0003 - Option 2				$ 8,488,740
0004 - Option 3				
0005 - Option 4				-
0006 - Option 5				-
			Total:	$38,246,106

Note:

(i) Internal Expenses. Internal expenses will be determined based on actual labor hours for the activities performed, multiplied by a single, fully-burdened FTE rate not subject to true-up, calculated for the Research & Development organization which will be working on the programs under this Agreement. This rate will be adjusted annually based on the CPI adjustment methodology outlined in the final cost proposal. The Contracting Officer will request documents supporting adjustments in the CPI.

(ii) External (Subrecipient or Affiliates) Expenses. External expenses will be billed based on actual third-party charges submitted to Regeneron.

(iii) Drug Supply. Drug supply manufactured at a Regeneron facility will be billed based on a fully-allocated cost methodology which includes direct variable, direct fixed and indirect cost allocations (See the 9/14/17 proposal). Drug manufactured by a third party contract manufacturer will be billed based on actual third party charges submitted to Regeneron.

(iii) G&A. G&A expenses will be billed for external expenses and drug supply based on a set rate not subject to true-up. A negotiated rate agreement or rate documentation shall be provided in the subrecipient agreement.

2. Under Article I: Overview of the Agreement

Paragraph A. Introduction, shall be amended by replacing references to "monoclonal antibodies" or "monoclonal antibody products" with the phrase "monoclonal antibodies, drugs or other therapies".

Delete and replace the following definition:
Subject Invention: Any Invention Made in the performance of work under this Agreement within the Field for which Recipient pursues a patent; provided that, all monoclonal antibodies, drugs and other therapies that are Inventions Made under this Agreement within the Field and that are developed as lead candidates under this Agreement will be deemed to be Subject Inventions.

3. Under Article II PERIOD OF PERFORMANCE, delete and replace as follows:

Line Item	Description of Services	Period of Performance
0001	Base Period-Generation and isolation and characterization of leads against PEPs, Eps, or REPs or host target(s), and generation of (humanized) mouse model for PEP, EP or REP	September 25, 2017-June 30, 2021
0002	Option 1-PMPD Production and in-vivo testing of lead therapies	September 25, 2017-June 30, 2022
0003	Option 2-Toxicology activities	September 25, 2017-May 31, 2021
0004	Option 3-IND enabling activities	June 30 2019-March 30, 2024
0005	Option 4-Clinical Study	July 30,2021-March 31, 2026
0006	Option 5-Additional Clinical Study	November 30, 2023-March 31, 2026

4. Under **ARTICLE IV: (MANAGEMENT OF THE PROJECT)**, Paragraph **A (Recipient/Government Joint Oversight Committee), is deleted and replaced as follows:**

Recipient/Government Joint OTAR Oversight Committee ("JOC") is comprised of 5 senior level members from Recipient (3 of which will be non-voting), 2 senior level Government participants, and the Other Transaction Agreement Officer (OTAO), Other Transaction Agreement Specialist (OTAS), and Other Transaction Technical Representative (OTTR) who will attend as non-voting participants. The parties may change the number of JOC participants upon mutual agreement. Additional representatives from either Party or external advisors may also be included in this body on an ad hoc basis, as dictated by the circumstances. Either party may substitute alternate senior level representatives, on either a temporary or ongoing basis, by providing advance written notice.

JOC Members:

Kimberly Armstrong, Ph. D.	BARDA	Chief, Therapeutics, Influenza and Emerging Infectious Disease Division/BAR
Ruben Donis, Ph.D.	BARDA	Director, Influenza and Emerging Infectious Disease Division/BARDA
Christos Kyratsous, Ph.D.	Regeneron	Vice President, Infectious Diseases and Viral Vector Technologies

Sumathi Sivapalasingam, MD	Regeneron	Senior Director, Clinical Experimental Sciences

Non-voting Attendees

Carl Newman	Other Transaction Agreement Officer and Other Transaction Agreement Specialist
Karl Erlandson	Other Transaction Agreement Representative
Leah Lipsich	VP Strategic Program Direction, Global Clinical Development
Regeneron ID scientist	(As assigned-depending on specific target)
Regeneron Program Manager	(As assigned)

The responsibility of the Recipient/Government Joint Oversight Committee is to mutually evaluate risks and progress of assets covered under this Agreement, endorse potential new assets and agree on modifications to the allocation of funding of activities covered under this Agreement. This committee will also jointly evaluate progress towards achievement of Portfolio Performance metrics (see Attachment 1, Section 1.1.1.1.) Decisions of the JOC will be made by consensus, with each Party having one (1) vote.

The Recipient/Government Joint Oversight Committee will meet approximately every six (6) months by phone, ad-hoc, via video conference, or in-person to review progress. The JOC will recommend the strategy to be covered under this Agreement during the subsequent funding period, as well as how Government and Recipient funding will be allocated across these activities. The recommendations would be submitted, as appropriate, to the relevant Recipient governance boards(s) for endorsement and decision. If endorsed by the Recipient and by the Government, the recommendations will be incorporated into the SOW and this Agreement through modifications as described in ARTICLE III. The Recipient will be solely responsible for the conduct of, and will have final decision making authority for activities within the SOW.

5. **ARTICLE V (AGREEMENT ADMINISTRATION)** is deleted and replaced as follows:

A. Administrative and contractual matters under this Agreement will be referred to the following representatives of the Parties:

Government Points of Contact
Other Transactions Agreement Specialist (OTAS)
Carl Newman
202-205-1156
Carl.Newman@hhs.gov

Other Transactional Agreement Officer (OTAO)
Carl Newman
202-205-1156
Carl.Newman@hhs.gov

Technical matters under this Agreement will be referred to the following representatives:

Government Points of Contract
Karl Erlandson, OTTR
Health Scientist, Therapeutics Branch, Influenza and Emerging Infectious Disease Division
202-692-4676
Karl.erlandson@hhs.gov

Alternate OTTR:

Kim Armstrong
Health Scientist, Chief, Therapeutics Branch, Influenza and Emerging Infectious Disease Division
(202)260-0130
Kimberly.armstrong@hhs.gov

Recipient Points of Contact
(b)(6)
Sr. Project Associate
Research Program Management
Regeneron Pharmaceuticals, Inc.
(b)(6)

6. Under **ARTICLE VII OBLIGATION OF FUNDING and FINANCIAL TERMS,** paragraph B, the table is deleted and replaced as follows:

NAME	Email invoices to	Address**
Carl A. Newman (OTAO)	Carl.newman@hhs.gov	ASPR-CMA BARDA O'Neill House Office Bldg 200 C Street, SW, 21C06 Washington, D.C. 20515
Karl Erlandson (OTTR)	Karl.erlandson@hhs.gov	ASPR BARDA O'Neill House Office Bldg 200 C Street, SW, 21C06 Washington, D.C. 20515
PSC	Psc_Invoices@psc.hhs.gov	
E-Room:	(As provided by the Government)	

7. Under **Article VIII OTHER TERMS AND CONDITIONS, paragraph E. (Title To and Disposition of Property) c. (Property Produced under this Agreement)** is deleted and replaced as follows:

Property Produced under this Agreement. Notwithstanding anything to the contrary in this Agreement, all right, title and interest in and to tangible Property produced under this Agreement shall vest with Recipient with no further obligation to the Government. With respect to any monoclonal antibodies, drugs or other therapies that are developed as lead candidates under this Agreement, if there are excess amounts of any such antibodies, drugs or other therapies following completion of all of Recipient's obligations and activities involving such antibodies, drugs or other therapies under this Agreement (including after the exercise of all Options) then, upon the Government's request and at the Government's cost, Recipient shall provide such antibodies, drugs or other therapies, as applicable, to the Government. In any such case, Recipient hereby grants to the Government a paid-up, nonexclusive, nontransferable, irrevocable, worldwide license in and to such antibodies, drugs or other therapies, as applicable, to exercise Government Purpose Rights except as expressly provided elsewhere in this Agreement.

8. Attached are the following documents which support the modified Base and Option 1:

1) Delete and replace Attachment 1 – Revised Statement of Work (SOW) dated May 9, 2019 (20 pages)

All other terms and conditions remain the same.

FOR THE UNITED STATES OF AMERICA
OFFICE OF ACQUISITION MANAGEMENT,
CONTRACTS & GRANTS SECRETARY
FOR PREPAREDNESS AND RESPONSE

Carl A. Newman -S Digitally signed by Carl A. Newman -S
DN: c=US, o=U.S. Government, ou=HHS, ou=OS, ou=People, cn=Carl A. Newman -S, 0.9.2342.19200300.100.1.1=2000066290
Date: 2019.05.31 14:56:22 -04'00'

(Signature) *(Date)*
Carl A. Newman,
Other Transaction Agreement Officer

FOR Regeneron Pharmaceuticals, Inc.

(b)(6) 5/30/19

(Signature) (Date)

(b)(6)

Robert E. Landry,
Executive Vice President, Finance and Chief Financial Officer, Regeneron Pharmaceuticals, Inc.

END OF MODIFICATION No. 0003 TO HHSO100201700020C